No. 89-243

In The Supreme Court of the United States October Term, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

MOTION and BRIEF FOR AMICUS CURIAE THE PROCTER & GAMBLE COMPANY IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

RICHARD C. WITTE
Counsel of Record
RONALD L. HEMINGWAY
THE PROCTER & GAMBLE COMPANY
Ivorydale Technical Center
Cincinnati, Ohio 45217
513/627-5666

Counsel for Amicus Curiae

American Reprographics Management, Inc.™ (312) 332-2764

No. 89-243

In The
Supreme Court of the United States
October Term, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

MOTION FOR AMICUS CURIAE THE PROCTER & GAMBLE COMPANY IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Pursuant to Rule 36.1 of this Court, The Procter & Gamble Company ("P&G") respectfully moves this Court for leave to file the attached brief *amicus curiae* in support of the petition for certiorari. Movant has been unable to secure the consent of respondent.

P&G (including its subsidiaries) is a manufacturer and marketer of food, drug, and cosmetic products which are subject to regulation by the Food and Drug Administration ("FDA"). Although the specific type of product at issue in this case is

medical devices, P&G believes the decision below directly affects a much broader range of products. Indeed, P&G submits that the decision below substantially erodes P&G's existing and potential future patent rights in the areas of nondrug food additives and products containing color additives.

P&G believes that its views will be helpful to the Court in understanding the broad national effect of the decision below, especially in the areas of food additives and color additives not directly at issue in the case. P&G also believes that its views will be helpful to the Court in emphasizing the importance of the petition.

Respectfully submitted,

Dated: August 31, 1989

RICHARD C. WITTE
Counsel of Record
RONALD L. HEMINGWAY
THE PROCTER & GAMBLE COMPANY
Ivorydale Technical Center
Cincinnati, Ohio 45217
513/627-5666

Counsel for Amicus Curiae

QUESTION PRESENTED

The Procter & Gamble Company adopts the following question presented by petitioner Eli Lilly and Company.

35 U.S.C. § 271(e)(1) provides that "it shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products"* (emphasis added).

The question presented is:

Whether the Court of Appeals erred as a matter of law by expanding the patent infringement exemption of 35 U.S.C. § 271(e)(1) beyond "drugs" and "veterinary biological products" to encompass, and thereby to erode patent protection for, medical devices, food additives, color additives, and all other FDA-regulated, nondrug products?

TABLE OF CONTENTS

TABLE OF AUTHORITIES

No. 89-243

In The
Supreme Court of the United States
October Term, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

BRIEF FOR AMICUS CURIAE THE PROCTER & GAMBLE COMPANY IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

The Procter & Gamble Company ("P&G") files this *amicus curiae* brief in support of the petition of Eli Lilly and Company ("Lilly") for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit, entered in the above-captioned proceeding on March 29, 1989.

INTEREST OF THE AMICUS CURIAE

P&G (including its subsidiaries) is a manufacturer and marketer of food, drug, and cosmetic products which are subject

to regulation by the Food and Drug Administration ("FDA").[1] P&G also is engaged in significant research and development in these areas. P&G relies substantially upon the patent system for protecting its hard-earned inventions that result from its investments and research efforts.

Although the type of product at issue in this case is medical devices, the Court of Appeals' holding directly affects a much broader range of products. The Court of Appeals stated:

> Accordingly, we hold that Section 271(e)(1) allows a party to make, use, or sell *any type* of "patented invention" if "solely" for the restricted uses stated therein.

(Pet. App. 7a)[2] (emphasis in original).

Thus, the Court of Appeals' decision substantially erodes P&G's existing and potential future patent rights in the areas of nondrug food additives and products containing color additives. The Court of Appeals' decision came as a surprise to P&G. To P&G's knowledge, no one, either in commentary or during the legislative process, had ever read the statutory language of 35 U.S.C. § 271(e)(1) the way the Court of Appeals reads it, *i.e.*, to apply to all products (in addition to drugs and veterinary biological products) regulated by the FDA or under other federal

---

[1] P & G is *not* a competitor of petitioner or respondent, or their subsidiaries, in the field involving the medical devices of this lawsuit.

[2] "Pet App. 7a" refers to page 7a of petitioner's appendix. P&G will refer to petitioner's appendix on several occasions using the same citation form.

laws.[3] In addition, Senator Orrin G. Hatch (principal author of the Senate Bill that enacted 35 U.S.C. §271(e)(1) into law) and Representative Carlos J. Moorhead (primary floor manager of that legislation in the House of Representatives) expressed their view in an *amicus* brief supporting a rehearing before the Court of Appeals that the legislative history demonstrates that Congress intended Section 271(e)(1) to apply only to drugs.

P&G has a strong interest in having this Court correct the erroneous Court of Appeals' decision and restore the full scope of patent protection for food and color additive products. Because all appeals concerning patent matters and Section 271(e)(1) are within the exclusive appellate jurisdiction of the Federal Circuit pursuant to 28 U.S.C. § 1295, P&G has no other forum to determine judicially that the infringement exemption of Section 271(e)(1) excludes nondrug food additives and color additives (used in foods and cosmetics), unless this Court grants certiorari.

ARGUMENT

This case raises a federal statutory issue of exceptional national importance. It involves a purely legal issue not within the particular competence of the Federal Circuit. The Court of Appeals clearly erred in its interpretation of Section 271(e)(1). These factors make this case precisely the type in which certiorari should be granted.

A. An Exceptionally Important Statutory Issue Is Before This Court

The Court of Appeals determined that infringing medical devices and other nondrug, FDA-regulated products are entitled

---

[3] *Compare* Goldstein, *The Drug Price Competition and Patent Term Restoration Act of 1984 Title II — Patent Extension Provisions*, 40 Food Drug Cosm. L.J. 363, 367 (1985) ("[W]hile the holding of *Roche v. Bolar* is reversed as to drugs, the implications of that case, as they relate to all regulated compounds other than human drugs, still remain in effect."); Flannery & Hutt, *Balancing Competition and Patent Restoration in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 307 (1985) (Section 271(e) (1) "does not include medical devices . . . food additives, color additives, or other related activities.")

to a limited noninfringement defense under Section 271(e)(1). P&G agrees with Judge Newman's conclusion in her dissent from the denial of Lilly's suggestion for rehearing in banc:

> The panel's judicial legislation has affected an important high-technology industry, without regard to the consequences for research and innovation or the public interest.

(Pet. App. 12a).

P&G further adds that the Court of Appeals' decision affects industries other than those for medical devices. These include the industries for FDA-regulated food additives, color additives, and other nondrug products. P&G joins in the persuasive reasons set forth by Lilly in its petition for certiorari demonstrating the exceptional importance of the federal statutory issue before this Court. The Court of Appeals' decision will have a substantial economic impact on the business of P&G and a negative impact on investment for pioneering developments in the areas of food and color additives.

For example, P&G conducts safety tests, typically costing millions of dollars, to obtain FDA approval for its patented food additive products. These safety tests may take from five to fifteen years to complete.[4] It takes another two or three years to obtain FDA approval for a food additive or color additive after filing a food or color additive petition. Thus, the complete FDA approval process, including safety testing, may take from seven to eighteen years and many millions of dollars to complete.

After P&G has paved the way for competitors by obtaining FDA approval for these pioneering inventions, competitors, in spite of any P&G patents, can use immediately the patented inventions in research to obtain FDA approval for new uses or manufacturing processes for these inventions under the Court of Appeals' interpretation of Section 271(e)(1). This can lead to a competitive advantage for P&G's competitors even though they

[4] P&G has filed for FDA approval for a food additive called olestra, which is a fat substitute product. The safety testing for olestra has taken nearly fifteen years.

did not undertake the substantial risk and expenses in inventing and then obtaining original FDA approval for the pioneering inventions. Thus, P&G now has lost the exclusive rights to its patented inventions in important research areas. The economic impact is substantial since P&G is deprived of the exclusive opportunity to develop new uses and manufacturing processes for these patented inventions. The net effect is to lessen the incentive for P&G and other innovative companies to invent and invest in pioneering products.

B. The Court of Appeals' Decision Is Clearly Erroneous

In reaching its decision, the Court of Appeals concluded that 35 U.S.C. § 271(e)(1) was ambiguous.[5] The Court of Appeals, therefore, resorted to the legislative history and concluded that it was the intent of Congress to overrule "in all of its ramifications" the prior decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984) (Pet. App. 7a). Notwithstanding the fact that the subject matter and holding of *Bolar* only involved drugs, the Court of Appeals concluded that it was the intent of Congress to immunize from patent infringement otherwise infringing activities conducted for regulatory purposes under any federal law regulating drugs or veterinary biological products, even if the product involved is not a drug or veterinary biological product. With respect to the Food, Drug and Cosmetic Act, for example, this means that such activities conducted with respect to seeking approval for the marketing of medical devices, food additives, and color additives are immunized, simply because the Act regulating them also regulates drugs.

The legislative history does not support the Court of Appeals' strange interpretation. The Court of Appeals did not cite any language from the legislative history, because there is none, stating in words or substance that FDA-regulated medical devices, food additives, color additives, and other nondrug

[5] P&G disagrees and submits that the plain language of Section 271(e)(1) clearly limits its infringement exemption to drugs and veterinary biological products.

products fall within the exemption of Section 271(e)(1). Lilly's petition for certiorari sets forth the substantial legislative references establishing that Section 271(e)(1) is directed solely to drugs. *See* Lilly's Petition for Certiorari, pp. 12-14.

Simply put, the Court of Appeals' decision constitutes impermissible judicial legislation. *See, e.g., United States v. Rutherford,* 442 U.S. 544, 555 (1979) ("Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy.").

CONCLUSION

The decision of the Court of Appeals, if left standing, will have enormous negative economic impact on America's innovative companies. Based upon the important national issue involved and the Court of Appeals' clear error, a grant of certiorari is fully justified, and even compelled, in this case.

Respectfully submitted,

/s/RICHARD C. WITTE

RICHARD C. WITTE
Counsel of Record
RONALD L. HEMINGWAY
THE PROCTER & GAMBLE COMPANY
Ivorydale Technical Center
Cincinnati, Ohio 45217
513/627-5666

Counsel for Amicus Curiae

Dated: August 31, 1989